zimmer spine	**510(k) SUMMARY** **InFix® Anterior Lumbar System**

Date of Summary Preparation:	December 20, 2013
Submitter:	Zimmer Spine, Inc. 7375 Bush Lake Road Minneapolis, MN 55439 USA
Establishment Registration Number:	2184052 (Minneapolis)
Company Contact (Primary):	Donna M. Semlak Senior Regulatory Affairs Specialist Office: 952.857.5643 Email Fax: 952.857.5843
Trade Name(s):	InFix® Anterior Lumbar System
Device Name (Common Name):	Intervertebral Body Fusion Device Vertebral Body Replacement
Device Classification:	Class II
Regulation Number(s) and Product Code(s)	21 CFR § 888.3080 / MAX 21 CFR § 888.3060 / MQP

Predicate Devices:

Predicates are indicated to accommodate the indication for use for the subject *InFix* System, added indication for intervertebral body fusion device (IBFD) and retain the indication for vertebral body replacement (VBR). The subject *InFix* System is claimed to be substantially equivalent to the following legally marketed predicate devices in the following table.

InFix® Anterior Lumbar Implant System Predicate Device Names	**Submission ID Number**	**Clearance Date**
InFix® Anterior Lumbar Device (System) *Original Applicant: Spinal Concepts* *Product Code: MQP*	K031672	August 07, 2003
Ardis Spacer *Original Applicant: Abbott Spine* *Product Code: MAX*	K073202	January 30, 2008

General Device Description:

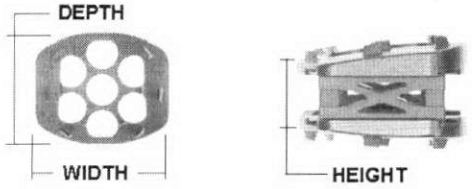
The *InFix* System is comprised of implants and two configurations of instrumentation. The subject InFix implants are the same design and dimensions as those described in *InFix* System, VBR submission K031672.

The *InFix* implant is comprised of two endplates and two struts, which are to be utilized together; with an optional endcap. The *InFix* System is provided in a range of angles and heights, including the instrumentation (accessories and instruments) necessary to implant the specific system. The current instrumentation is retained in aluminum trays. The new proposed instrumentation is retained in stainless trays.

The *InFix* implant is manufactured from implantable grade Ti-6AL-4V alloy that conforms to ASTM F-136. The implant is comprised to two opposing Endplates (provided in 0°, 3°, 6° and 9° angles) supported by two vertical Struts available in a range of heights, allowing the surgeon to fix the vertebrae in proper anatomical alignment and lordosis. Each of the Struts includes a load-sharing mechanism that allows a limited amount of strain across the fusion mass while supporting the load bearing surfaces. An Ultra High Molecular Weight Polyethylene (UHMWPE) Endcap may be placed inside the implant prior to packing it with bone graft. The Endcap serves as an optional block of the posterior opening in the implant construct to assist in containing the material inside. Holes in the Endplates provide space for bone in-growth while angled spikes penetrate the vertebral endplates and provide resistance to rotation and migration.

The *InFix* implant is designed for direct placement between two vertebral bodies. Component sizes and dimensions and the InFix implant depth, width and height are shown below. All dimensions are in millimeters. Strut heights are in 2mm increments.

Size	*InFix* Struts	*InFix* Endplates	
	Heights (mm)	Depth (mm)	Width (mm)
Small	8-14	24	29
Medium	8-14	26.5	32
Large	8-14	29	35



The *InFix* implant is assembled and locked in-situ; bone graft is then inserted within the device and up to the anterior rim of the vertebral body.

InFix is implanted using a set of specialized instruments. The subject *InFix* System specialized instruments (stainless steel trays) are listed in the *InFix Anterior Lumbar System* Surgical Technique Guide. The current InFix System instruments (aluminum trays) are listed in the InFix Anterior Lumbar Device Surgical Technique Guide. Both instrumentation sets facilitate the insertion and removal of the *InFix* implants. The *InFix* implant is provided for single use only.

Indications for Use:

When us as a vertebral body replacement device, the *InFix*® System is intended for use in the thoracic and/or lumbar spine (T3-L5) to replace a collapsed, damaged or unstable vertebral body resected or excised (i.e., partial vertebrectomy procedures) due to tumor or trauma (i.e., fracture). The *InFix* System is designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period. The *InFix* implant is intended to be used with bone graft.

When used as an intervertebral body fusion device the *InFix* System is indicated for use with autogenous bone graft at one or two contiguous levels in the lumbosacral region (L2-S1) in the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Patients with previous non-fusion spinal surgery at involved level may be treated with the device. Patients should be skeletally mature and have had six months of non-operative treatment. When used as an intervertebral body fusion device, the *InFix* implant is intended to be used with supplemental fixation.

For both of the indications listed above, the *InFix* implant is intended to be implanted via an open anterior approach.

Summary of Technological Characteristics:

The *InFix* System shares the same technological characteristics its predicate device, InFix System, Anterior Lumbar Device (K031672), The technological characteristics include the same intended use as spinal spacers, the same mechanical and functional design; the same range of sizes, materials and the same substantially equivalent performance characteristics.

Ardis (K073202) was selected as predicate device because it already obtain the IBFD indications and have similar technological characteristics.

The subject and predicate implant are a hollow taper design in various height, width and length options, which provides space for bone in-growth. Implants provided for single use only.

InFix System and the predicates are implanted using a set of specialized instruments. These instruments facilitate the access, insertion and removal of the implants.

Summary of Performance Testing:

Non-clinical testing included components of the proposed *InFix* System were reviewed and tested appropriately for design controls; i.e. design verification. The test results conclude the *InFix* System to be substantially equivalent to the predicate devices, In-Fix and Ardis.

- Bench Testing for Vertebral Body Replacement (VBR) was conducted per ASTM F2077 for Static and Dynamic Torsion, Static and Dynamic Compression Bending confirming the *In-Fix* implant performance is acceptable for its intended use; the same intended use as the predicate device InFix.
- Additional Bench Testing for Intervertebral Body Fusion Device (IBFD) was conducted per ASTM F2077 for Static and Dynamic Compression Shear; which included Subsidence testing per ASTM F2267 confirming the *InFix* implant performance is acceptable for its intended use; the same intended use as the predicate device, Ardis.
- Cadaver testing is conducted to ensure the *InFix System* performs as intended and to ensure substantially equivalent to the predicate devices.
- Sterilization is conducted under ISO 17665 and AAMI TIR12, to ensure substantially equivalent to the predicate devices. Dry time and cleaning instructions were also assessed.
- Biocompatibility Assessment per ISO 10993-1 was conducted to ensure the *InFix System* materials are biocompatible based on the same materials to the predicate devices.

The *InFix System* testing concluded the performance, intended use and fundamental scientific technology of the *Infix* implant remains unchanged and is substantially equivalent to the predicate, InFix and Ardis devices.

Substantial Equivalence:

Zimmer Spine considers the subject *InFix* System product performance to be substantially equivalent to the predicate; InFix and Ardis devices because they are used to treat the same conditions, represent a basic design concept in terms of safety and effectiveness. There is no change to the implant mechanical performance, no change to the device functional scientific technology and testing supports the addition of the proposed Intervertebral Body Fusion Device indication.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 20, 2013

Zimmer Spine, Incorporated
Ms. Donna M. Semlak
Senior Regulatory Affairs Specialist
7375 Bush Lake Road
Minneapolis, Minnesota 55439

Re: K132790
Trade/Device Name: InFix® System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, MQP
Dated: September 26, 2013
Received: September 27, 2013

Dear Ms. Semlak:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

REVISED Dec 10, 2013

INDICATIONS FOR USE STATEMENT

510(k) Number (if known) K132790

Device Name(s): *InFix® System*

Indications for Use

When used as a vertebral body replacement device, the *InFix®* System is intended for use in the thoracic and/or lumbar spine (T3-L5) to replace a collapsed, damaged or unstable vertebral body resected or excised (i.e., partial vertebrectomy procedures) due to tumor or trauma (i.e., fracture). The *InFix* is designed to restore the biomechanical integrity of the anterior and middle spinal column even in the absence of fusion for a prolonged period. The *InFix* implant is intended to be used with bone graft.

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For both of the indications listed above, the *InFix* implant is intended to be implanted via an open anterior approach.

Prescription Use ____X_____ AND/OR Over-the Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD

Division of Orthopedic Devices